

This is an attempt to revise Title 17 with the least amount of changes for APA compliance. Only those revisions deemed essential have been made and are in RED. Every attempt was made to leave the original Title 17 sections intact when possible to avoid APA problems. Repealed language is lined through for identification. The original numbering system has remained the same for ease in comparison with current Title 17 regulations.

OOR Note: The following OOR comments and suggested amendments are proposed in the light of attempting to modify the current provision as little as possible, yet make it clear such that there is only one interpretation of the provision if that provision is to be retained. The committee will find that OOR frequently cites the amendments proposed in the redraft of the regulation text dated January 23, 2007. The reason for this citation is to prevent duplication of the work already conducted by OOR in light of the significant increase in workload for OOR that is the case due to the reorganization of CDHS into the Department of Public Health (DPH) and Department of Health Care Services (DHCS) on July 1, 2007. The committee may determine other language if it desires or may repeal any provision it does not see as necessary to ensure competence. All suggested amendments made to the retained text by OOR are provided in blue with additions stipulated in single underline and repeals in strikeout. OOR comments in the comments section are not in colored text because colors were used by the previous reviewers for the subcommittee and confusion would occur with the use of colored text by OOR. Minor edits were made to OOR's comments and suggested amendments by the Office of Legal Services.

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS
TITLE 17. PUBLIC HEALTH
DIVISION 1. STATE DEPARTMENT OF HEALTH SERVICES
CHAPTER 2. LABORATORIES
SUBCHAPTER 1. SERVICE LABORATORIES
GROUP 8. FORENSIC ALCOHOL ANALYSIS AND BREATH ALCOHOL ANALYSIS
ARTICLE 1. GENERAL

This database is current through 05/12/06, Register 2006, No. 19.

s 1215. Authority.

~~Chapter 5 Sections 436.50-436.63 of Part 1 of Division 1 of the Health and Safety Code.~~

s 1215.1. **Definitions.**

(a) "Alcohol" means the unique chemical compound, ethyl alcohol, with the exception that reference in these regulations to compounds to be avoided as skin

Comment [GH1]: Repealed as a Rule 100 change.

Comment [DoHS2]: Page: 3
OOR: Amendments to definitions were proposed in the regulations redraft dated 1/26/06. Some of those still would be advisable. All the amendments suggested in the proposed regulation text are for the purposes of clarity of the current language so that the use of the term is understandable in the operating standards and does not suggest multiple meanings.

antiseptics includes the generic class of organic compounds known as alcohols.

(b) "Forensic Alcohol Analysis" means the ~~practical application use~~ of specialized devices, instruments, and methods by ~~trained laboratory forensic alcohol~~ personnel to measure the concentration of ~~ethyl~~ alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or traffic violations.

(c) "Breath Alcohol Analysis" means ~~analysis an examination~~ of a sample of a person's expired breath, using a breath testing instrument designed for this purpose, in order to determine the concentration of ~~ethyl~~ alcohol in the person's blood.

(d) "Concentration" means the weight amount of alcohol contained in a unit volume of liquid or a unit volume of gas under specified conditions of temperature and pressure; in the case of a solid tissue specimen, "concentration" means the weight amount of alcohol contained in a unit weight of specimen.

(e) "Forensic Alcohol Laboratory" means a place at which specialized apparatus, instruments, and methods are used by ~~trained laboratory forensic alcohol~~ personnel to measure the concentration of alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or in traffic violations; this may be an activity of a laboratory engaged in activities other than ~~forensic~~ alcohol analysis.

(f) "Forensic Alcohol Supervisor" means a person employed by a forensic alcohol laboratory who can be responsible for all aspects of the performance of forensic alcohol analysis and for the supervision of personnel who perform such analysis.

(g) "Forensic Alcohol Analyst" means a person employed by a forensic alcohol laboratory who performs the ~~technical procedures methods~~ of forensic alcohol analysis.

(h) "Forensic Alcohol Analyst Trainee" means a person employed by a forensic alcohol laboratory for the purpose of receiving comprehensive practical experience and instruction in the technical procedures of forensic alcohol analysis under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.

(i) "Method" means the steps used by a trained person to make a measurement of alcohol concentration ~~in a sample or specimen~~.

(j) "Instrument" or "Device" means any item or combination of items of equipment used to make a measurement of alcohol concentration; ~~simple and complex devices are included in this meaning~~.

~~(k) "License" means a document issued by the State Department of Health to a~~

~~laboratory to perform the tests referred to in the Health and Safety Code, Sections 436.51 and 436.52.~~

(l) "Sample" or "Specimen" means a representative portion of breath, blood, urine, or tissue or of an artificially constituted material, **taken** for the purpose of measuring its alcohol concentration.

(m) "Alveolar" refers to the smallest air sacs in the lungs and to that portion of the expired breath which is in equilibrium with respect to alcohol with the immediately adjacent pulmonary blood.

~~(n) "Department" means the California State Department of Health and its duly authorized representatives.~~

ARTICLE 2. REQUIREMENTS FOR FORENSIC ALCOHOL LABORATORIES

s 1216. Authorization Requirement.

~~(a) Every laboratory performing forensic alcohol analysis shall have a valid license issued in accordance with the provisions of these regulations.~~

(1) Forensic alcohol analysis shall be performed only by persons who meet the qualifications set forth in **these regulations section 1216.1** for forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst **trainees**.

(A) A trainee may perform forensic alcohol analysis only under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.

~~(2) The Department shall not be limited by these regulations in performing functions in administration of the alcohol analysis and licensing program.~~

s 1216.1. Qualifications for **Licensing** **to perform forensic alcohol analysis**.

(a) A **forensic alcohol** laboratory meets the qualifications **for licensing to perform forensic alcohol analysis** by:

(1) Employing at least one forensic alcohol **supervisor**. If forensic alcohol analysis is performed by persons other than forensic alcohol supervisors, such persons shall meet the qualifications set forth in **these regulations this section** for forensic alcohol analysts or forensic alcohol analyst trainees;

(2) Maintaining a quality control program in forensic alcohol analysis procedures **as specified in section 1220.3**;

Comment [GH3]: Repealed as a Rule 100 change.

Comment [DoHS4]: Page: 4
OOR: "taken" is a term that does not readily apply to "artificially constituted material." Could the term "obtained" be used instead?

Comment [GH5]: Repealed as a Rule 100 change.

Comment [DoHS6]: Page: 4
OOR: Possible reasoning to include in the ISOR to support this "rule 100" change might involve a statement that the term "Department" is repealed because the committee did not determine that the direct involvement of the CDHS in a regulatory program was necessary to ensure the competence of the labs or employees and as a result, the committee chose to remove all reference to the "Department" from the current regulation text. Although Health and Safety Code section 100725 states that CDHS shall enforce the statutes and regulations, the law does not require CDHS's direct involvement in a regulatory program.

Comment [GH7]: The subcommittee intention is to repeal the entire Section 1216. This d ... [1]

Comment [GH8]: Repealed as a Rule 100 change.

Comment [DoHS9]: Page: 5
OOR: the term "these regulations" is vague and can be construed to ... [2]

Comment [DoHS10]: Page: 5
OOR: The question arises as to whether the requirements in (a) ... [3]

Comment [DoHS11]: Page: 5
OOR: Possible reasoning to include in the ISOR to support the ... [4]

Comment [GH12]: Repealed as a Rule 100 change.

Comment [GH13]: Repealed as a Rule 100 change.

Comment [GH14]: JUSTIFICATION: The deletions are required by changes in the law. However, t ... [5]

Comment [GH15]: Repealed as a Rule 100 change.

Comment [DoHS16]: Page: 5
OOR: This language is not truly "regulatory," but can be used if ... [6]

Comment [DoHS17]: Page: 5
OOR: Do national standards make the requirement that a person v ... [7]

Comment [DoHS18]: Page: 5
OOR: Is the QA program specified in section 1220.3 based on comp ... [8]

(3) ~~Demonstrating satisfactory performance in a proficiency testing program conducted by or approved by the Department; Meeting the proficiency testing requirements specified in Health and Safety Code Section 100702.~~

(4) ~~Passing such on-site inspections as the Department may require;~~

(5) Showing ability to meet the requirements set forth in these regulations.

(b) These qualifications shall be maintained at all times by each licensed laboratory.

~~(c) The Department may deny a license or renewal thereof, or take disciplinary action against a licensee, for failure to maintain these qualifications in a manner which meets the Department's standards for approval.~~

~~(d) Whenever a licensed laboratory employing only one forensic alcohol supervisor loses that person, the Department may upon petition of the laboratory extend the license for a period not exceeding 90 days during which time the laboratory shall hire another forensic alcohol supervisor.~~

(1) Such an extension shall be contingent on the laboratory's having in its employ at least one forensic alcohol analyst and upon the laboratory's successfully demonstrating to the Department continued competence in forensic alcohol analysis through such proficiency tests, examinations, and on-site inspections as the Department may require.

(e) A forensic alcohol supervisor is a person who meets the following qualifications:

(1) Possesses a baccalaureate or higher degree, or an equivalent, in any physical or natural science in chemistry, biochemistry, or other appropriate discipline as determined by the Department;

(2) Has two years of experience in performing forensic alcohol analysis, such experience to include experience in interpretation and correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of ethyl alcohol; or, in lieu of such two years of experience, satisfactorily completes a training course approved by the Department, such training course to include at minimum the following schedule of subjects:

(A) Value and purpose of forensic alcohol analysis, including breath alcohol analysis;

(B) Physiological action of alcohol;

Comment [let19]: Current section repealed as a Rule 100 change. Alternative language inserted, see comment below.

Comment [GH20]: Stipulation of the location of the proficiency testing requirements is necessary to inform the forensic alcohol laboratories of the statutory requirements and provide guidance to the location of the mandates.

Comment [GH21]: Repealed as a Rule 100 change.

Comment [DoHS22]: Page: 5
OOR: This language is very vague. It offers no understanding of what is necessary to "show ability...". If the committee wants to require something along this track, it is preferred that the language be reworked as in the redraft of 1/26/06. However, as all the other sections maintain a requirement that the lab shall meet some mandate or standard, it is not really clear why it is necessary for this to be stated in this section. This was a qualification for licensing and made sense as such even though it was still vague and the forensic alcohol program had needed to offer clarity through its application processes. It truly is a different ... [9]

Comment [let23]: Rule 100 change

Comment [DoHS24]: Page: 5
OOR: This again is a subsection that does not make much sense in light of the repeal of licensing require ... [10]

Comment [GH25]: Repealed as a Rule 100 change.

Comment [GH26]: Repealed as a Rule 100 change.

Comment [GH27]: Repealed as a Rule 100 change.

Comment [DoHS28]: Page: 6
OOR: Again, this is not regulating language. OOR recommends the language used in the redraft c ... [11]

Comment [GH29]: Justification: All scientific disciplines that are relevant to the practice of forensic alcohol analysis and insures the comp ... [12]

Comment [GH30]: Repealed as a Rule 100 change. (OOR: to support the "rule 100" change, the committee will need to determine that it c ... [13])

Comment [DoHS31]: Page: 6
OOR: Have the listed subjects been determined necessary to ensure competence by an accrediting ... [14]

- (C) Pharmacology and toxicology of alcohol;
- (D) Laboratory methods of alcohol analysis;
- (E) Instruments and procedures for breath alcohol analysis;
- (F) Practical laboratory demonstration of the student's ability to perform alcohol analysis;
- (G) Interpretation of results of alcohol analysis, including correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of alcohol;
- (H) Court testimony;
- (I) Court decisions regarding chemical tests of alcohol to determine alcohol influence; and
- (J) Requirements of [these regulations Title 17 of the California Code of Regulations, sections 1215 to 1222.2 inclusive](#);
- (3) Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department;
- (4) **Demonstrates the ability to adhere to the provisions of these regulations**; or (in lieu of (1) and (2) ~~above~~)
- (5) Either is a person who, prior to January 1, 1971, qualified as director of a clinical laboratory operating under the provisions of the California Business and Professions Code, or is a person who, for a period of one year prior to January 1, 1971, has been employed in the activities of a forensic alcohol supervisor, **or be qualified by the Department of Health Services as a Forensic Alcohol Supervisor on or before [\(we will insert date for the expected filing the public notice with OAL\)](#) the effective date these regulations are promulgated.**
- (f) A forensic alcohol analyst is a person who meets the following **qualifications**:
- (1) **Possess a baccalaureate or higher degree in one of the physical or natural sciences that includes one year (2 semesters or 3 quarters) of general chemistry including lab work. Successfully completes at least 60 semester hours, or their equivalent in quarter hours, of college-level courses, including 8 hours of general chemistry and 3 hours of quantitative analysis;**
- (2) Successfully completes a training period in forensic alcohol analysis on

Comment [GH32]: Repealed as a Rule 100 change.

Comment [DoHS33]: Page: 7
OOR- It is appreciated that this is the current language, but it is vague. This language was supported by the forensic alcohol program's guidance documents that described how one was to demonstrate this ability. Since there will no longer be a department determining this ability, this is a questionable provision to maintain. Unless the regulation describes something that assists the forensic alcohol supervisor in knowing how he is to "demonstrate" his ability and provide guidance for the courts so this can be measured, OOR recommends this provision be repealed and organize the grandparenting subsection differently to assist with logical flow. If the committee elects to keep this provision, then the ISOR will need to offer some statement that labs will determine this for themselves so that courts will not be put in the position of making decisions regarding this demonstration each time a supervisor is there. Of course, if the labs are doing this themselves, then what is the point of making the provision? ... [15]

Comment [DoHS34]: Page: 7
OOR: This grandparenting language was from the initial promulgation of the FAL regulations and is 36 years old. Are there any persons in practice now who are qualified as FA supervisors based on this language? If not, it would be reasonable to repeal the language and only ... [16]

Comment [GH35]: Justification: Addition of this statement allows for all applicable grandparenting under this provision. (OOR- There is a mechanism for making these kinds of stipulations in regulation. We will set the date when we get closer to the date for public noticing. Is CDHS still qualifying persons for these v ... [17])

Comment [DoHS36]: Page: 7
OOR: Please refer to the note in DoHS 28.

Comment [GH37]: Justification: Proposed regulations require analysts have a science degree as a minimal qualification, consistent with forensic science community requirements for analytical work. The original language should be deleted. (OOR- You will need reasoning that demonstrates that this increases ... [18])

Comment [GH38]: Justification: The term "period" is vague and has been deleted for clarity.

forensic or clinical specimens in a forensic alcohol laboratory or in a clinical laboratory;

(3) Performs during the training period a minimum of 25 analyses of alcohol concentration in blood samples, at least half of which contain alcohol;

(4) Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department;

(5) Demonstrates ability to adhere to the provisions of these regulations; or (in lieu of (1), (2), and (3) above)

(6) Either is a person who, prior to January 1, 1971, was a clinical laboratory technologist licensed under the provisions of the California Business and Professions Code, or is a person who, for a period of one year prior to January 1, 1971, has been employed in the activities of a forensic alcohol analyst or be qualified by the Department of Health Services as a Forensic Alcohol Analyst on or before (we will insert date for the expected filing the public notice with OAL) the effective date these regulations are promulgated.

(g) A forensic alcohol analyst trainee is a person who meets the following qualifications:

(1) Meets the educational qualification set forth as (f)(1) for a forensic alcohol analyst;

(2) Is employed by a licensed forensic alcohol laboratory.

ARTICLE 3. LICENSING PROCEDURES

s 1217. Forensic Alcohol Laboratory License.

(a) Upon receipt of a completed application which shows ability to meet the requirements set forth in these regulations, and upon payment of any required fee, the Department shall submit such proficiency test samples and perform such examinations as are required for that laboratory to complete the qualifications.

(b) Upon the laboratory's successfully completing all the qualifications, the Department shall issue to the applicant laboratory a forensic alcohol laboratory license.

s 1217.1. Renewal of Licenses.

Comment [GH39]: References to "clinical" have been deleted as the regulations pertain to the defined forensic lab only and the training should be specific to forensic alcohol testing. (OOR- While it is perfectly acceptable for you to make the requirements more stringent, you will need to explain why are you doing this with the intent of looking to demonstrate that this is what is necessary to ensure competence in light of the fact that it was not required before to ensure competence. Simply stating that only forensic training is best is not enough. You must provide something that supports that clinical laboratory training does not provide the training needed for conducting forensic work. Is there evidence from accrediting bodies that those without only forensic training are less competent or make more errors? Perhaps you could offer some discussion of forensic laboratory standards being different from clinical laboratory standards, assuming this is the case. Certainly, forensic handling procedures are different and that could be cited as part of the reasoning. If you know that no forensic lab will hire an analyst that does not have training in a forensic lab, then you could cite that as supporting your reasoning, but essentially, you will need evid... [19]

Comment [GH40]: Justification: The term "period" is vague and has been deleted for clarity.

Comment [GH41]: Repealed as a Rule 100 change.

Comment [DoHS42]: Page: 7
OOR- Please see comments in DoHS 33 comment. Issues are the same here.

Comment [GH43]: Justification: Addition of this statement allows for all applicable grandparenting under this provision. (OOR- Please see OOR comments in DoHS 34 and 35.)

Comment [DoHS44]: Page: 8
OOR- The ISOR will need to discuss briefly or at least cross reference to the reasoning for the requirement of a greater amount of education in amended regulations of qualifications for the trainee. A note that offers that trainees become analysts on ... [20]

Comment [GH45]: Repealed as a Rule 100 change.

Comment [GH46]: The entire contents of Article 3 have been repealed as a Rule 100 change.

~~(a) Licenses under these regulations shall be renewed as required by the Department as long as the activity requiring authorization continues. Renewal shall be contingent upon the laboratory continuing in the qualifications set forth in these regulations.~~

~~(1) A forensic alcohol laboratory license shall be valid from January 1 to December 31 of a calendar year. Applications for renewal and applicable fees shall be submitted to the Department on or before October 1 of each year.~~

~~(2) Failure to apply for renewal shall result in forfeiture after a period of three months from the day on which the application for renewal should have been submitted, with the exception that the Department may grant a temporary extension under special circumstances.~~

~~(3) An application for renewal shall not list as a forensic alcohol analyst trainee any person who fails to comply with the requirements of Section 1216.1 (f) (4) within a period of one year after he was first listed with the Department as a trainee. The Department may extend this period for a justifiable reason, such as illness.~~

~~s 1217.2. Application Forms.~~

~~Application for a license and renewal thereof, shall be made on forms furnished by the Department. The applicant shall set forth all pertinent information called for by the form.~~

~~s 1217.3. Report of Change or Discontinuance.~~

~~(a) A person responsible for the operation of a forensic alcohol laboratory shall report to the Department in writing within 30 days any change in qualified personnel who may be performing forensic alcohol analysis, change of ownership, change of address or change or discontinuance of an activity authorized under these regulations.~~

~~(b) Such reports shall be made on forms furnished by the Department and shall set forth all pertinent information called for by the form.~~

~~(c) Persons who formerly qualified as forensic alcohol supervisors or forensic alcohol analysts in another laboratory may be required to demonstrate again their ability to meet the requirement of Section 1216.1 (e) (3) or 1216.1 (f) (4) using the method, apparatus and facilities of the forensic alcohol laboratory which newly lists them in such a Report of Change or Discontinuance.~~

~~s 1217.4. License Implications.~~

~~Licenses issued under these regulations shall not imply approval of anything carried out by a laboratory other than what is specified on the document.~~

~~s 1217.5. Licensing Records.~~

~~Forensic Alcohol Laboratory Licenses shall become part of permanent records available to the courts for legal proceedings or to the Department.~~

~~s 1217.6. Inspection and Additional Requirements.~~

~~(a) Display of Licenses. Licenses issued under these regulations shall be displayed on request to representatives of the Department.~~

~~(b) Access to Premises. The Department may enter at all reasonable times upon any laboratory for the purpose of determining whether or not there is compliance with the provisions of these regulations.~~

~~s 1217.7. Surveys and Proficiency Tests.~~

~~(a) Laboratories having been licensed or applying for licensing as forensic alcohol laboratories shall be subject to on-site surveys by representatives of the Department, the results of which must meet the requirements of these regulations, and shall accept periodic evaluation samples, perform analyses and report the results of such analyses to the Department.~~

~~(b) These analytical results shall be used by the Department to evaluate the accuracy of the forensic alcohol analyses performed by the laboratory, and the results must meet the requirements of these regulations.~~

~~s 1217.8. Fees and Other Procedures.~~

~~The annual application fee for a Forensic Alcohol Laboratory License or its renewal shall be one hundred dollars (\$100). A laboratory operated by the state, city or county or other public organization shall be exempt from the annual application fee requirement. Other procedures in the administration of these regulations shall be carried out as set forth in Chapter 5 (commencing with section 436.50) of Part 1 of Division 1 of the Health and Safety Code. Such other procedures include suspension or revocation of license, denial of license, and disciplinary action.~~

~~ARTICLE 4. TRAINING OF PERSONNEL~~

Comment [GH47]: The entire contents of Article 4 have been repealed as a Rule 100 change. (OOR- This is arguably not a Rule 100 change. The statute repeals the licensing of the laboratories; however, it does not say that the CDHS shall not approve training of personnel. OOR recommends that the ISOR reasoning offer that the committee determined that CDHS was not the appropriate body to determine the suitability of training for personnel nor was CDHS the appropriate body to require and monitor examinations or other such tests nor is CDHS oversight necessary in these areas to ensure the competence of employees of the lab, and the reasons for that determination. This extra reasoning will help support the repeal as part of non-emergency rulemaking in the APA.)

~~s 1218. Training Program Approval.~~

~~Any organization, laboratory, institution, school, or college conducting a course of instruction for persons to qualify under these regulations shall submit a course summary and list of instructors and their qualifications to the Department for approval.~~

~~s 1218.1. Additional Requirements.~~

~~At the discretion of the Department, any phase or portion of a training program shall be subject to alteration in an effort to update the program as technological advances are made or if a portion has been judged inappropriate.~~

~~s 1218.2. Contracts.~~

~~The Department may contract with persons it deems qualified to administer such practical tests and written or oral examinations as may be required under these regulations. This section shall not be construed to authorize the delegation of any discretionary functions conferred on the Department by law, including, but not limited to, the evaluation of tests and examinations.~~

ARTICLE 5. COLLECTION AND HANDLING OF SAMPLES

s 1219. General.

~~Samples taken for forensic alcohol analysis and breath alcohol analysis shall be collected and handled in a manner approved by the Department. The identity and integrity of the samples shall be maintained through collection to analysis and reporting.~~

Comment [GH48]: Repealed as a Rule 100 change. (OOR: reasoning is recommended to address that the committee determined that CDHS approval of collection and handling procedures is not necessary to ensure competence of labs and employees.)

s 1219.1. Blood Collection and Retention.

(a) Blood samples shall be collected by venipuncture from living individuals as soon as feasible after an alleged offense and only by persons authorized by Section ~~13354~~ 23158(a) of the Vehicle Code.

Comment [DoHS49]: Page: 11
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

(b) Sufficient blood shall be collected to permit duplicate determinations.

Comment [GH50]: Vehicle Code section 13354 was renumbered in Stats 1985, c.735, §4 to Vehicle Code section 23158(a).

(c) Alcohol or other volatile organic disinfectant shall not be used to clean the skin where a specimen is to be collected. Aqueous benzalkonium chloride (zephiran), aqueous merthiolate or other suitable aqueous disinfectant shall be used.

Comment [GH51]: NOTE FOR COMMITTEE: Use of merthiolate was not deleted to avoid making a change to this section. (OOR: In light of the OAL determination, it is reasonable to make the amendment if the committee so desires.)

(d) Blood samples shall be collected using sterile, dry hypodermic needles and syringes, or using clean, dry vacuum type containers with sterile needles. Reusable equipment, if used, shall not be cleaned or kept in alcohol or other volatile organic solvent.

(e) The blood sample shall be deposited into a clean, dry container which is closed with an inert stopper.

(1) Alcohol or other volatile organic solvent shall not be used to clean the container.

(2) The blood shall be mixed with an anticoagulant and a preservative.

(f) When blood samples for forensic alcohol analysis are collected post-mortem, all practical precautions to insure an uncontaminated sample shall be employed, such as:

(1) Samples shall be obtained prior to the start of any embalming procedure. Blood samples shall not be collected from the circulatory system effluent during arterial injection of embalming fluid. Coroner's samples do not need a preservative added if stored under refrigeration.

(2) Care shall be taken to avoid contamination by alcohol from the gastrointestinal tract directly or by diffusion therefrom. The sample shall be taken from a major vein or the heart.

(g) In order to allow for analysis by the defendant, the remaining portion of the sample shall be retained for one year after the date of collection.

(1) In coroner's cases, blood samples shall be retained for at least 90 days after date of collection.

(2) Whenever a sample is requested by the defendant for analysis and a sufficient sample remains, the forensic alcohol laboratory or law enforcement agency in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in a clean container together with a copy or transcript of the identifying information carried on the original sample container.

s 1219.2. Urine Collection and Retention.

(a) The only approved urine sample shall be a sample collected no sooner than twenty minutes after first voiding the bladder.

Comment [GH52]: NOTE TO COMMITTEE: Use of preservatives was not revised to avoid making a change to this section. (OOR: In light of the OAL determination, it is reasonable to make the amendment if the committee so desires.)

Comment [DoHS53]: Page: 12
OOR: The regulation does not say who approves the urine sample? This could be rewritten like the rest of the section: "A urine sample shall be collected . . ."

(b) The specimen shall be deposited in a clean, dry container which also contains a preservative.

(c) In order to allow for analysis by the defendant, the remaining portion of the sample shall be retained for one year after the date of collection.

(1) Whenever a sample is requested by the defendant for analysis and a sufficient sample remains, the forensic alcohol laboratory or law enforcement agency in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in a clean container together with a copy or transcript of the identifying information carried by the original sample container.

Comment [DoHS54]: Page: 12
OOR: The language in subsections (c) and (c)(1) are inconsistent. Subsection (c) refers to labs because that is what you propose to be regulating and (c)(1) refers to labs and law enforcement agencies retaining the specimen. If law enforcement has the specimen, how is the lab to "retain for one year after the date of collection" as specified in (c)? This language needs to be redrafted if you wish to retain these provisions.

s 1219.3. Breath Collection.

A breath sample shall be expired breath which is essentially alveolar in composition. ~~The quantity of the breath sample shall be established by direct volumetric measurement.~~ The breath sample shall be collected only after the subject has been under continuous observation for at least fifteen minutes prior to collection of the breath sample, during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked.

Comment [GH55]: Repealed as a Rule 100 change.
New H&S code dictates instruments on the DOT list that can be used. Laboratories no longer need to perform this testing. (OOR- Recommend providing further explanation, because it is not clear how the instruments specified make it unnecessary to specify this quantity of sample. OAL will probably not understand this either, so please explain so it is clear how this is a Rule 100 change.)

ARTICLE 6. METHODS OF FORENSIC ALCOHOL ANALYSIS

s 1220. General.

(a) All laboratory methods used for forensic alcohol analysis shall be subject to standards set forth in this Article.

(b) Each licensed forensic alcohol laboratory shall have ~~on file with the Department detailed~~, up-to-date written descriptions of each method it uses for forensic alcohol analysis.

Comment [DoHS56]: Page: 13
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

Comment [GH57]: Repealed as a Rule 100 change.

Comment [GH58]: Repealed as a Rule 100 change. (OOR- Recommend that the "on file" part be repealed as well because the question arises "on file" with whom from the phrasing that remains. It may be reasonable to require that the lab will have these descriptions "on site.")

(1) Such descriptions shall be immediately available to the person performing an analysis ~~and shall be available for inspection by the Department on request.~~

(2) Each such description shall include the calibration procedures and the quality control program for the method.

Comment [GH59]: Repealed as a Rule 100 change. (OOR- Recommend that you remove the "and shall be available for inspection on request" part because the question arises as to inspection by whom and why.)

s 1220.1. Standards of Performance.

Comment [DoHS60]: Page: 13
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

(a) Methods for forensic alcohol analysis shall meet the following standards of performance:

(1) The method shall be capable of the analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 5 percent of the value; these limits shall be applied to alcohol concentrations which are 0.10 **0.08** grams per 100 milliliters or higher;

Comment [GH61]: Repealed as a Rule 100 change. (OOR- This is not really a rule 100 change. The change is for the same reason as offered in GH62, GH71, and GH82. It is best to explain this in the ISOR as a change in the CA Vehicle Code standard of legal intoxication and the need of the labs to be able to accurately test at this level.)

(2) The method shall be capable of the analysis of ethyl alcohol with a specificity which is adequate and appropriate for traffic law enforcement.

Comment [GH62]: Justification: Reflects change in CA Vehicle Code from 0.10 to 0.08 by Stats. 1989, ch.479.

(3) The method should be free from interference from anticoagulants and preservatives added to the sample;

Comment [GH63]: Repealed as a Rule 100 change. (OOR- So who is it evaluated by? Anybody who chooses to? Defense attorneys, maybe? Courts? And what if they choose to evaluate it by some other means or measures? What is anyone going to do about it? This is a remnant of the repealed CDHS licensing provisions. OOR recommends that all of subsection (b) be repealed because it is meaningless without the "by the Department" statement in it.)

(4) Blood alcohol results on post-mortem samples shall not be reported unless the oxidizable substance is identified as ethyl alcohol by qualitative test;

(5) The method shall give a test result which is always less than 0.01 grams of alcohol per 100 milliliters of blood when living subjects free of alcohol are tested.

(b) The ability of methods to meet the standards of performance set forth in this Section shall be evaluated by the Department using a laboratory's proficiency test results and such ability must meet the requirements of these regulations.

Comment [DoHS64]: Page: 14
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

s 1220.2. Standards of Procedure.

Comment [GH65]: NOTE to FARC: Use of dry gas units has not been introduced here.

(a) Methods for forensic alcohol analysis shall meet the following standards of procedure:

(1) The method shall be calibrated with standards which are water solutions of alcohol.

Comment [GH66]: Justification: Use and acceptance of NIST traceable standards in the scientific community (such as CA licensed clinical) has long been in existence due to their enhanced international reliability. This change includes the alternative use of NIST traceable standards within the laboratory setting. (OOR- This sounds like it is some sort of standard established in the laboratory community. If so, is it written anywhere? If so, the ISOR needs to cite and provide that document to support the inclusion of this in regulation. Is it in the CLIA requirements?) ... [21]

(A) Such alcohol solutions are secondary standards.

(B) Each forensic alcohol laboratory shall purchase National Institute of Standards and Technology (NIST) traceable secondary alcohol standards, or establish the concentration of each lot of secondary alcohol standards it prepares using uses, whether prepared or acquired, by an oxidimetric method which employs a primary standard, such as United States National Bureau of Standards NIST potassium dichromate, when preparing the standards.

Comment [GH67]: Justification: The National Bureau of Standards is now known as NIST.

(C) The forensic alcohol laboratory shall verify the concentration of any new secondary standards used in the method by analyzing the new secondary standard concurrently with a previously analyzed secondary standard.

Comment [GH68]: Justification: This is a general scientific practice utilized in scientific laboratories. The purpose of including it here is to mandate this practice by the laboratories. (OOR- Please provide some written source or other evidence of this practice as a ... [22])

(2) The procedure shall include blank and secondary alcohol standard samples at least once each day that samples are subjected to forensic alcohol analysis.

(A) The blank and secondary alcohol standard samples shall be taken through all steps of the method used for forensic alcohol analysis of samples.

(3) The procedure shall also include analysis of quality control reference samples as described in Section 1220.3 and shall include at least duplicate analyses of samples for forensic alcohol analysis.

(A) A quality control reference sample shall not be taken from the same lot of alcohol solution which is used as a secondary alcohol standard.

(4) Alcohols or other volatile organic solvents shall not be used to wash or rinse glassware and instruments used for alcohol analysis;

(5) All instruments used for alcohol analysis shall be in good working order and routinely checked for accuracy and precision.

s 1220.3. Quality Control Program.

(a) Methods for forensic alcohol analysis shall be performed in accordance with the following quality control program:

(1) For each method of forensic alcohol analysis it performs, each forensic alcohol laboratory shall make or acquire a suitable quality control reference material containing alcohol, a sample of which it shall analyze along with each set of samples; the alcohol concentration in the reference material shall be between ~~0.10~~ 0.08 and 0.20 grams per 100 milliliters of liquid;

(2) For each lot of quality control reference material, the laboratory shall determine a mean value of at least 20 replicate analyses, at a rate of no more than 2 analyses per day, with the method used for analysis of samples for forensic alcohol analysis;

(3) Acceptable limits of variation for the method shall be set as follows:

(A) The lower limit shall be calculated by subtracting, from the mean value, 0.01 grams per 100 milliliters;

(B) The higher limit shall be calculated by adding, to the mean value, 0.01 grams per 100 milliliters;

(4) At least one sample of the quality control reference material shall be analyzed with each set of samples analyzed for the purpose of forensic alcohol analysis;

Comment [DoHS69]: Page: 14
OOR-There is vague language here, and it may allow for any definition of "good working order" and "routinely checked" to apply. More specifics are needed. Further, it seems the labs could not meet the other procedure standards unless their machines worked and were checked. Why is this requirement necessary to ensure competence? Could it be repealed and the same outcome achieved?

Comment [DoHS70]: Page: 15
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

Comment [GH71]: Justification:
Reflects change in CA Vehicle Code from 0.10 to 0.08 by Stats. 1989, ch.479.

(5) Whenever analysis of the quality control reference material is outside the acceptable limits, the method shall be regarded to be in error, and a forensic alcohol supervisor shall take remedial action to investigate and correct the source of error;

(6) Until such time as the error has been corrected, as shown by return of the analysis of the quality control reference material to values within the acceptable limits, no samples shall be analyzed for the purpose of forensic alcohol analysis.

s 1220.4. Expression of Analytical Results.

(a) With the exception of tissue analysis, all analytical results shall be expressed in terms of the alcohol concentration in blood, based on the number of grams of alcohol per 100 milliliters of blood, **or in breath, based on the number of grams of alcohol per 210 liters of breath.**

(1) The symbols, grams %, %, and % (W/V), shall be regarded as acceptable abbreviations of the phrase, grams per 100 milliliters of liquid **or grams of alcohol per 210 liters of breath.**

(b) Analytical results shall be reported to the second decimal place, deleting the digit in the third decimal place when it is present.

(c) Blood alcohol concentrations less than 0.01% in living subjects may be reported as negative.

(d) Blood alcohol concentrations less than 0.02% on post-mortem blood samples may be reported as negative.

(e) A urine alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 1.3 milliliters of blood is equivalent to the amount of alcohol in 1 milliliter of urine.

~~(f) A breath alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 2,100 milliliters of alveolar breath is equivalent to the amount of alcohol in 1 milliliter of blood.~~

(g) Tissue analysis results shall be expressed in terms of a weight amount of alcohol in a unit weight of the specimen.

Comment [GH72]: This is a Rule 100 change. Justification: Vehicle Code Section 23152(a) was amended to read "For purposes of this article and Section 34501.16, percent, by weight, of alcohol in a person's blood is based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath." (OOR- When was this amendment? Please cite the chaptered bill and date.)

Comment [GH73]: This is a Rule 100 change. Justification: Vehicle Code Section 23152(a) was amended to read "For purposes of this article and Section 34501.16, percent, by weight, of alcohol in a person's blood is based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath." (OOR- When was this amendment? Please cite the chaptered bill and date.)

Comment [GH74]: Justification is the updated CVC, 2100:1 ratio no longer used. (OOR- When was this amended? As above? Please cite the chaptered bill and date.)

ARTICLE 7. REQUIREMENTS FOR BREATH ALCOHOL ANALYSIS

s 1221. General.

~~Breath alcohol analysis shall be performed in accordance with standards set forth in this Article.~~

s 1221.1. Authorized Procedures.

(a) Breath alcohol analysis shall be performed only with instruments and related accessories which meet the standards of performance set forth in these regulations.

(b) Such instruments may be used for the analysis of breath samples in places other than ~~licensed~~ forensic alcohol laboratories and by persons other than forensic alcohol supervisors, forensic alcohol analysts and forensic alcohol analyst trainees only if such places and persons are under the direct jurisdiction of a governmental agency or ~~licensed~~ forensic alcohol laboratory.

(1) Breath alcohol analysis by persons other than forensic alcohol supervisors, forensic alcohol analysts and forensic alcohol analyst trainees shall be restricted to the immediate analysis of breath samples collected by direct expiration by the subject into the instrument in which the measurement of alcohol concentration is performed.

(2) Except for the requirements of Section 1220.4, such immediate analysis shall not be subject to the requirements of Article 6.

~~s 1221.2. Standard of Performance.~~

~~(a) Instruments for breath alcohol analysis shall meet the following standard:~~

~~(1) The instrument and any related accessories shall be capable of conforming to the "Model Specifications for Evidential Breath Testing Devices" of the National Highway Traffic Safety Administration of the U.S. Department of Transportation, which were published in the Federal Register, Vol. 49, No. 242, Pages 48854-48872, December 14, 1984, and are hereby adopted and incorporated.~~

~~(b) The ability of instruments and any related accessories to conform to the standard of performance set forth in this section shall be tested by the U.S. Department of Transportation.~~

s 1221.3. Approved Instruments.

Comment [GH75]: Repealed as a Rule 100 change. (OLS - The term "places other than forensic alcohol laboratories" should be made more specific by replacing it with a term such as "breath alcohol laboratories" or "law enforcement laboratories" and defining that term in section 1215.1 to clarify that it includes use of breath alcohol analysis by law enforcement agencies. Under the new law governing forensic alcohol laboratories, places authorized to perform breath alcohol analysis would fall within the general category of "laboratories." (See Health and Safety Code sections 100700, 100701) See also comment in DoHS54.)

Comment [GH76]: Repealed as a Rule 100 change.

Comment [GH77]: Repealed as a Rule 100 change. H&S 100701

~~(a) Only such types and models of instruments and related accessories as are named in the "Conforming Products List" published in the Federal Register by the National Highway Traffic and Safety Administration of the U.S. Department of Transportation shall be used for breath alcohol analysis in this State.~~

Comment [GH78]: Repealed as a Rule 100 change.

Breath alcohol instruments and calibrating units used in breath alcohol analysis shall meet the requirements specified in Health and Safety code Section 100701.

Comment [GH79]: Rule 100 change. It is not necessary to duplicate the statute in regulation. The subcommittee determined that the specification was necessary for the purposes of informing the forensic alcohol laboratories of the existence and location of the statutory requirements for the instruments used to calibrate for and conduct breath alcohol analysis. This should be an acceptable reason to duplicate statute in regulations according to the APA.

s 1221.4. Standards of Procedure.

(a) Procedures for breath alcohol analysis shall meet the following standards:

(1) For each person tested, breath alcohol analysis shall include analysis of 2 separate breath samples which result in determinations of blood alcohol concentrations which do not differ from each other by more than 0.02 grams per 100 milliliters.

(2) The accuracy of instruments shall be determined.

Comment [DoHS80]: Page: 17
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

(A) Such determination of accuracy shall consist, at a minimum, of periodic analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 0.01 grams % of the true value; these limits shall be applied to alcohol concentrations from 0.10 0.08 to 0.30 0.25 grams %. The reference sample shall be provided by a forensic alcohol laboratory.

Comment [GH81]: FARC: note this does not specify using dry gas or wet bath calibrating units. Do we want to differentiate the standard accuracy tests with dry gas/wet bath units vs the lab staff checking the calibration of an instrument using secondary standard solutions only???? Advise.

1. Such analysis shall be performed by an operator as defined in Section 1221.4 (a)(5), and the results shall be used by a forensic alcohol laboratory to determine if the instrument continues to meet the accuracy set forth in Section 1221.4 (a)(2)(A).

Comment [GH82]: Justification: Reflects change in CA Vehicle Code from 0.10 to 0.08 by Stats. 1989, ch.479.

(B) For the purposes of such determinations of accuracy, "periodic" means either a period of time not exceeding 10 days or following the testing of every 150 subjects, whichever comes sooner.

Comment [GH83]: Justification: Not all instruments that measure alcohol concentration are linear (accurate) above the 0.25 grams % levels. For this reason, the upper limit of accuracy and precision was reduced to 0.25 grams, which is well above the 0.08 grams % legal limit for driving under the influence laws.

(3) Breath alcohol analysis shall be performed only with instruments for which the operators have received training, such training to include at minimum the following schedule of subjects:

(A) Theory of operation;

(B) Detailed procedure of operation;

(C) Practical experience;

(D) Precautionary checklist;

(E) Written and/or practical examination.

(4) Training in the procedures of breath alcohol analysis shall be under the supervision of ~~persons who qualify as~~ forensic alcohol supervisors, forensic alcohol analysts or forensic alcohol analyst trainees, ~~or law enforcement officers who are qualified instrument operators as specified in subsection (a)(5) and who are approved by forensic alcohol supervisors or forensic alcohol analysts in a~~ licensed forensic alcohol laboratory.

~~(A) After approval as set forth in Section 1218, the forensic alcohol laboratory is responsible for the training and qualifying of its instructors.~~

(5) An operator shall be a forensic alcohol supervisor, forensic alcohol analyst, forensic alcohol analyst trainee or a person who has completed successfully the training described under Section 1221.4 (a) (3) and who may be called upon to operate a breath testing instrument in the performance of his duties.

(6) Records shall be kept for each instrument to show the frequency of determination of accuracy and the identity of the person performing the determination of accuracy.

(A) Records shall be kept for each instrument at a licensed forensic alcohol laboratory showing compliance with this Section.

s 1221.5. Expression of Analytical Results.

Results of breath alcohol analysis shall be expressed as set forth in Section 1220.4.

ARTICLE 8. RECORDS

s 1222. General.

~~Forensic alcohol laboratories and law enforcement agencies shall maintain records which clearly represent their activities which are covered by these regulations. Such records shall be available for inspection by the Department on request.~~

s 1222.1. Forensic Alcohol Laboratory Records.

(a) Each laboratory which is licensed to perform forensic alcohol analysis shall

Comment [GH84]: Rule 100 change; DoHS no longer qualifies individuals as FAS, FAA, or FATs. (OOR- The reasoning for the repeal is not understandable. What does CDHS not approving or qualifying these classifications have to do with repealing the language "persons who qualify as"? The regulation specifies qualifications that persons must meet for labs to call these persons by a particular classification. The labs have to determine if these persons qualify for a particular classification, so the phrase "persons who qualify as" still appears to be relevant.)

Comment [DoHS85]: Page: 18
OOR: What is the process of approval for law enforcement officers by FA supervisors or analysts? What are the required qualifications of the officers? Can the FA supervisors and analysts decide this for themselves? Is the lab to decide this? How many supervisors or analysts must approve since the plural is used, two? more? Do you really mean one? This process and criteria for qualification will either need to be described in regulation or the ISOR will need to specify that the lab may conduct this approval in any manner it desires. Of course, then you cannot say that the labs must only "approve" experienced operators and the point then becomes why do they have to approve at all. Why cannot the law enforcement ... [23]

Comment [GH86]: Justification: Due to the simplicity of use of breath alcohol instruments currently approved by the USDOT, crime laboratory staff should have the authority to delegate some of the breath instrument training fun ... [24]

Comment [GH87]: Rule 100 change.

Comment [DoHS88]: Page: 18
OOR- Section 1218 is repealed, so this subsection is repealed unless you want to simply repeal the "After approval as set forth in Section 1218," part and maintain the rest. The repeal of the rest of this subdi ... [25]

Comment [GH89]: Rule 100 change.

Comment [DoHS90]: Page: 19
OOR: The current regulation has no meaning without the concept of inspection from an outside entity. This made sense when CDHS licensed the labs, but does not now.

Comment [GH91]: Repealed as a Rule 100 change.

Comment [GH92]: Repealed as a Rule 100 change.

keep the following records for a period of at least three years:

- (1) An up-to-date record of persons in its employ who are qualified as forensic alcohol supervisors and forensic alcohol analysts; the record shall include the qualifications of each such person, including education, experience, training and performance in proficiency tests and examinations;
- (2) A list of persons in its employ who are forensic alcohol analyst trainees, the date on which each such person began his training period and the number and results of analyses performed during the training period;
- (3) Records of samples analyzed by that laboratory under these regulations, their results and the identity of persons performing the analyses;
- (4) Records of the quality control program;
- (5) Records of laboratory performance evaluation in alcohol analysis as shown by results of proficiency tests;
- (6) Records of such determinations of accuracy of breath testing instruments as a laboratory may perform for law enforcement agencies;
- (7) Records of such training as a laboratory may provide to persons who operate breath testing instruments for law enforcement agencies.

s 1222.2. Breath Alcohol Analysis Records.

(a) Each agency shall keep the following records for breath testing instruments which are under its jurisdiction:

- (1) Records of instrument determinations of accuracy;
- (2) Records of analyses performed, results and identities of the persons performing analyses;
- (3) At the location of each instrument, the precautionary checklist to be used by operators of the instrument.

Comment [DoHS93]: Page: 19
OOR- Since these record keeping requirements were part of the needs of CDHS to conduct its inspections for licensing, what is the point of them now? You can say this is a Rule 100 change from the perspective of eliminating the phrase, but then the point of the regulation comes into question. Do labs need to maintain these records for three years for some other reason? Is it for the courts? Is three years adequate for that purpose? Is a regulation requiring this record keeping necessary? Is this needed for the purpose of ensuring the competence of the lab or its employees? The ISOR should explain the purpose of this section beyond the Rule 100 change in order to demonstrate why it is not being repealed, and if this is not in the ISOR, it is likely that this will need to be explained in response to public comments on this point. It is a good practice to head off public comments by having a strong and comprehensive ISOR to support your actions in a regulation package. It will save much grief in the public process part of regulation promulgation.

Page 3: [1] Comment [GH7]**Gary Harris**

The subcommittee intention is to repeal the entire Section 1216. This draft only repeals paragraph (a) and (2) as Rule 100 changes.

Page 3: [2] Comment [DoHS9]**Dept. of Health Services**

Page: 5

OOR: the term “these regulations” is vague and can be construed to mean all the regulations in the CCR. While this is likely not to be the meaning the public will ascribe to the term, It has been OOR’s experience to have OAL find the use of the term “these regulations” to be vague and unclear due to this possible broad interpretation of the term. It is suggested that the committee remove the term and use a specific cross reference to replace it in current text.

Page 3: [3] Comment [DoHS10]**Dept. of Health Services**

Page: 5

OOR: The question arises as to whether the requirements in (a)(1) and (a)(1)(A) are standards that are used by accrediting bodies or some other national or local group to ensure competence of labs or employees. There will need to be some such justification to support the retention of these requirements in regulation.

Page 3: [4] Comment [DoHS11]**Dept. of Health Services**

Page: 5

OOR: Possible reasoning to include in the ISOR to support the determination that this repeal is a “rule 100” change is that the 2004 statute repealed the licensing requirement for FALs and since the committee views licensing as CDHS’s only role in the current regulation text, the committee determined the statute operationally repealed all requirements in current regulation related to licensing and CDHS’s role in that process. In addition, the reasoning needs to offer that the committee has also determined that no other role for CDHS is necessary to ensure the competence of labs and employees. However, the committee could determine that CDHS has some role that is necessary to ensure the competence of laboratories and employees, and could specify that role in the proposed regulations. Since the regulation text draft of the subcommittee did not contain any reference to any such role for CDHS, it is assumed that at least the subcommittee does not see CDHS as having any other role. If the committee concurs, the repeal of all references to licensing or CDHS having an action or requirement will be presented as a rule 100 change because all current text containing a CDHS role exists to support the licensing program that was repealed by operation of law.

Page 3: [5] Comment [GH14]**Gary Harris**

JUSTIFICATION: The deletions are required by changes in the law. However, to insure competent forensic alcohol analysis, the regulations must articulate minimal quality control requirements including such proficiency testing as required by H&S 100702. (OOR: Further reasoning for the ISOR might include that the text is amended to reference the statute to inform the regulated public of the location of the requirements for proficiency testing in the Health and Safety Code.)

Page 3: [6] Comment [DoHS16]**Dept. of Health Services**

Page: 5

OOR: This language is not truly “regulatory,” but can be used if it is the committee’s desire. OOR would recommend that the language format offered in the 1/26/06 redraft be used instead, as it is regulatory rather than suggestive of the requirements. However, as offered above, if the proposed regulations are intended to be standards that are self-enforced by the labs and may be used by the courts, the nuances of legal language are not truly critical to the purpose and likely will not be an issue with OAL.

Page 3: [7] Comment [DoHS17]**Dept. of Health Services**

Page: 5

OOR: Do national standards make the requirement that a person with the qualifications of the FA supervisor is necessary to ensure the competence of the labs or employees? This job classification was not included in the draft of January 2006 and OOR does not recall anyone offering that this supervisor was a necessary component of the lab to ensure competence or to be

accredited or anything else. This is especially important because the qualifications for the education of the supervisor and analyst are slightly different and it will be necessary to offer the reasons for why this is the case. It does not logically flow from the reading of the text and, since it is necessary to propose the need for all retained provisions, the need for the supervisor might need specific justification versus the global offering that the retained provisions meet a national standard or something to the end.

Page 3: [8] Comment [DoHS18]

Dept. of Health Services

Page: 5

OOR: Is the QA program specified in section 1220.3 based on components in the standards of the accrediting organizations? Is there some other body that proposes these components as necessary to ensure competence? Or perhaps the committee can cite the FAL program's experience with its requirement of these components as ensuring competence. CLIA uses proficiency testing as a QA mechanism. Does it require other specific mechanisms that could be cited as applied in the requirements of the QA program in these regulations?

Page 4: [9] Comment [DoHS22]

Dept. of Health Services

Page: 5

OOR- This language is very vague. It offers no understanding of what is necessary to "show ability...". If the committee wants to require something along this track, it is preferred that the language be reworked as in the redraft of 1/26/06. However, as all the other sections maintain a requirement that the lab shall meet some mandate or standard, it is not really clear why it is necessary for this to be stated in this section. This was a qualification for licensing and made sense as such even though it was still vague and the forensic alcohol program had needed to offer clarity through its application processes. It truly is a different situation now that licensing is no longer at issue. Showing ability to collect samples, run analysis methods, keep records, etc. is a question of "showing" to whom? The laboratories are going to be self-regulating, and if they have a quality control program and pass the statutory proficiency testing, should they not also have the capability to meet these other standards, which are specified that they have to meet in other sections anyway? An alternative to offering the greater specificity is to simply repeal this language. It truly is unenforceable as written now and could prove difficult if the courts start interpreting what the labs have to do to "show ability." If it is kept as written, then the ISOR should offer that this is something that the labs must determine for themselves. But of course if this is the case, then why state it in law if the lab can truly do anything it wants and that this "shows ability"? OOR recommends this subsection be repealed.

Page 4: [10] Comment [DoHS24]

Dept. of Health Services

Page: 5

OOR: This again is a subsection that does not make much sense in light of the repeal of licensing requirements. This requirement is something that is standard in regulation text that has an enforcement component that involves CDHS action. It flows in licensing regulations from the criteria to be licensed needing to be maintained because the licensing is an action that happens at a distinct point in time, and then in theory, the licensee could decide after that point not to continue to meet the criteria set as necessary to be licensed. In this case, there is no distinct point in time when a lab becomes a forensic alcohol lab. The lab makes this determination for itself, and it is something that is a continuous process of decision that happens every time the lab accepts a specimen for analysis. That is, if the lab calls itself a forensic alcohol lab, then it legally is if it meets the requirements of this section. Requiring that the lab has to continue to meet the qualifications does not really logically flow in this specific situation. It is difficult for OOR to discern the need for this regulation, but if the committee decides it still wishes to make this statement, then something explaining the idea that labs might call themselves a forensic alcohol lab one day and not the next might need to be offered.

Page 4: [11] Comment [DoHS28]

Dept. of Health Services

Page: 6

OOR: Again, this is not regulating language. OOR recommends the language used in the redraft of 1/26/06, but if the committee wishes to retain this language, it may, as there is no qualifying process by CDHS or any other governmental agency and so anyone who has the qualifications

listed can call themselves a forensic alcohol supervisor, analyst, or trainee. This is something the labs will have to determine for themselves as to how they will assess these qualifications and assign their personnel to the work regardless of the person's possession of the listed qualifications. OOR also recommends that the formatting be altered if the current qualifications are to be used, as they currently flow in a confusing manner and can be easily adapted to offer greater clarity with the grandparenting component that is included.

Page 4: [12] Comment [GH29]

Gary Harris

Justification: All scientific disciplines that are relevant to the practice of forensic alcohol analysis and insures the competence of those performing forensic alcohol analysis are included. This additionally provides uniformity in the field of practice. The original vague language previously used, such as "appropriate" has been deleted. The enhanced educational requirement for analysts to possess a degree is consistent and in compliance with the majority of the forensic science community and accrediting body requirements. (OOR requests that copies of the accrediting body standards to support this assertion be provided to the committee. They will be needed for the rulemaking file in duplicate. A question arises regarding the need for supervisors to have a degree if the standards cited to support the reasoning is only for analysts. While supervisors usually would have been analysts at some point and should be at least as qualified as the folks they supervise, the need for justification here is for the classification of supervisor. The reasoning needs to support that and providing accrediting standards that require supervisors to have specific degrees would be very helpful to support the reasoning for this requirement.)

Page 4: [13] Comment [GH30]

Gary Harris

Repealed as a Rule 100 change. (OOR: to support the "rule 100" change, the committee will need to determine that it does not see a role for CDHS in course approval as necessary to ensure the competence of labs or employees.)

Page 4: [14] Comment [DoHS31]

Dept. of Health Services

Page: 6

OOR: Have the listed subjects been determined necessary to ensure competence by an accrediting body or some other expert source? It might be possible to simply cite the experience of CDHS in enforcing this requirement over the years as the basis for the assertion that these subjects are the necessary subjects to ensure competence. If the committee believes that is the case, are these the subjects, or are there other subjects more likely to ensure competence?

Page 5: [15] Comment [DoHS33]

Dept. of Health Services

Page: 7

OOR- It is appreciated that this is the current language, but it is vague. This language was supported by the forensic alcohol program's guidance documents that described how one was to demonstrate this ability. Since there will no longer be a department determining this ability, this is a questionable provision to maintain. Unless the regulation describes something that assists the forensic alcohol supervisor in knowing how he is to "demonstrate" his ability and provide guidance for the courts so this can be measured, OOR recommends this provision be repealed and organize the grandparenting subsection differently to assist with logical flow. If the committee elects to keep this provision, then the ISOR will need to offer some statement that labs will determine this for themselves so that courts will not be put in the position of making decisions regarding this demonstration each time a supervisor is there. Of course, if the labs are doing this themselves, then what is the point of making the provision law, as the lab can do whatever it wants and state it meets the requirements?

Page 5: [16] Comment [DoHS34]

Dept. of Health Services

Page: 7

OOR: This grandparenting language was from the initial promulgation of the FAL regulations and is 36 years old. Are there any persons in practice now who are qualified as FA supervisors based on this language? If not, it would be reasonable to repeal the language and only include the language that speaks to the CDHS qualified supervisors as of the specified date. If there is someone in practice who is qualified based on the pre-1971 language, then the question arises if that person would still be qualified because he is currently qualified by CDHS or because of this

grandparenting language in current regulation. This is a question that program will have to help answer.

Page 5: [17] Comment [GH35]

Gary Harris

Justification: Addition of this statement allows for all applicable grandparenting under this provision. (OOR- There is a mechanism for making these kinds of stipulations in regulation. We will set the date when we get closer to the date for public noticing. Is CDHS still qualifying persons for these various positions or have they already stopped doing this? The answer impacts on the date we can set.)

Page 5: [18] Comment [GH37]

Gary Harris

Justification: Proposed regulations require analysts have a science degree as a minimal qualification, consistent with forensic science community requirements for analytical work. The original language should be deleted. (OOR- You will need reasoning that demonstrates that this increased level of qualification is necessary. You offered above in the supervisor section that there are accrediting body standards that support this. Citing such standards will be necessary to support this increased requirement. Of course, since it has not been necessary before, who will be impacted by this even though there is grandparenting in this package? It is possible there are people who are in this process of not yet being approved and who do not have degrees. If there are, you need to address this. If not, and I suggest that you conduct some research to be reasonably certain this is the case, then you need to state this. You might want to do a poll of your labs and find out if this is an issue. Also, why are chemistry with lab educational requirements in this amendment and not in the supervisor's requirements. The supervisor's requirements seem to be less than those for the analyst. While you may do this, you will need to provide a reason for the difference in the ISOR.)

Page 6: [19] Comment [GH39]

Gary Harris

References to "clinical" have been deleted as the regulations pertain to the defined forensic lab only and the training should be specific to forensic alcohol testing. (OOR- While it is perfectly acceptable for you to make the requirements more stringent, you will need to explain why are you doing this with the intent of looking to demonstrate that this is what is necessary to ensure competence in light of the fact that it was not required before to ensure competence. Simply stating that only forensic training is best is not enough. You must provide something that supports that clinical laboratory training does not provide the training needed for conducting forensic work. Is there evidence from accrediting bodies that those without only forensic training are less competent or make more errors? Perhaps you could offer some discussion of forensic laboratory standards being different from clinical laboratory standards, assuming this is the case. Certainly, forensic handling procedures are different and that could be cited as part of the reasoning. If you know that no forensic lab will hire an analyst that does not have training in a forensic lab, then you could cite that as supporting your reasoning, but essentially, you will need evidence based reasoning to support this more stringent requirement.)

Page 6: [20] Comment [DoHS44]

Dept. of Health Services

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OOR- The ISOR will need to discuss briefly or at least cross reference to the reasoning for the requirement of a greater amount of education in amended regulations of qualifications for the trainee. A note that offers that trainees become analysts on completion of the training would suffice to support the change.

Page 12: [21] Comment [GH66]

Gary Harris

Justification: Use and acceptance of NIST traceable standards in the scientific community (such as CA licensed clinical) has long been in existence due to their enhanced international reliability. This change includes the alternative use of NIST traceable standards within the laboratory setting. (OOR- This sounds like it is some sort of standard established in the laboratory community. If so, is it written anywhere? If so, the ISOR needs to cite and provide that document to support the inclusion of this in regulation. Is it in the CLIA requirements?)

Page 12: [22] Comment [GH68]

Gary Harris

Justification: This is a general scientific practice utilized in scientific laboratories. The purpose of including it here is to mandate this practice by the laboratories. (OOR- Please provide some written source or other evidence of this practice as a standard in scientific laboratories. Also, please provide some statement that explains what can happen if labs do not conduct this verification. This is the dotting "i's" and crossing "t's" of writing a statement of reasons for proposed regulation text and can greatly save time in responding to public comment in the public process of regulation promulgation.)

Page 17: [23] Comment [DoHS85] Dept. of Health Services

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OOR: What is the process of approval for law enforcement officers by FA supervisors or analysts? What are the required qualifications of the officers? Can the FA supervisors and analysts decide this for themselves? Is the lab to decide this? How many supervisors or analysts must approve since the plural is used, two? more? Do you really mean one? This process and criteria for qualification will either need to be described in regulation or the ISOR will need to specify that the lab may conduct this approval in any manner it desires. Of course, then you cannot say that the labs must only "approve" experienced operators and the point then becomes why do they have to approve at all. Why cannot the law enforcement agencies decide? All this will need to be explained in the ISOR.

Page 17: [24] Comment [GH86] Gary Harris

Justification: Due to the simplicity of use of breath alcohol Instruments currently approved by the USDOT, crime laboratory staff should have the authority to delegate some of the breath instrument training functions to experienced law enforcement instrument operators. (OOR- What would be needed to be considered an "experienced" instrument operator?)

Page 17: [25] Comment [DoHS88] Dept. of Health Services

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OOR- Section 1218 is repealed, so this subsection is repealed unless you want to simply repeal the "After approval as set forth in Section 1218," part and maintain the rest. The repeal of the rest of this subdivision appears to be related to the repeal of "persons who qualify as" in subdivision (a)(4). What is the rationale for this repeal? See OOR comment GH84.